State of California—Health and Human Services Agency
California Department of Public Health

RONALD CHAPMAN, MD, MPH
Director & State Health Officer

EDMUND G. BROWN JR.
Governor

July 16, 2012 AFL 12-35

TO: All Facilities

SUBJECT: Hospira Injectable Drug Products: Recall – Visible Particulates from Defective Glass Vials

The California Department of Public Health is advising all facilities to take the following actions based on an urgent message from the Food and Drug Administration (FDA):

Immediately discontinue use and distribution, and quarantine Hospira Injectable Drug Products of specific lot and batch numbers, containing:

- Carboplatin
- Cytarabine
- Paclitaxel
- Methotrexate

Please see ***Attachment A: Recalled Hospira Injectable Drug Products distributed in the United States*** (attached) for the list numbers, batch numbers, and expiration dates of the specifically recalled products. [Please see http://www.fda.gov/Safety/Recalls/ucm311971.html for information regarding products distributed outside of the United States, if needed.]

The FDA and Hospira have issued a nationwide recall of certain injectable drug products due to visible particles embedded in the glass located at the neck of the vial. There is a potential for product to come into contact with the embedded particles and for particles to be dislodged into the solution. In the event that particulate matter was injected into a patient, there could be a potential for patient injury where medical intervention would be required. Signs and symptoms might include bleeding, bruising, inflammation, itching, rash, chest pain and respiratory symptoms.

Hospira has completed an investigation and has attributed the root cause to a supplier glass defect. Corrective and preventative actions have been identified and initiated. Hospira is arranging for return or replacement of all recalled products.

Anyone with an existing inventory should stop use and distribution, quarantine the product, and call Stericycle at 1-888-628-0734, between the hours of 8am to 5pm EDT, Monday through Friday to arrange for return of the product. Replacement product from unaffected lots is available and no drug shortages are expected. To order replacement

product, call Hospira Customer Care at 1-877-976-7747, between the hours of 8am to 5pm CDT, Monday through Friday. For medical inquiries, please contact Hospira Medical Communications at 1-800-615-0187, at any time.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of these products to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax.

Online: https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm

Regular mail: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

Fax: 1-800-FDA-0178

For mail or fax reporting, please use FDA form 3500, available at: http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf or by request by calling 1-800-332-1088.

Thank you for your prompt attention to this matter.

Sincerely,

Original signed by Debby Rogers

Debby Rogers, RN, MS, FAEN
Deputy Director
Center for Health Care Quality

Attachment A: Recalled Hospira Injectable Drug Products distributed in the United States

ATTACHMENT A

Recalled Hospira Injectable Drug Products distributed in the United States

Product	List Number	Batch Number	Expiration Date
Carboplatin Injection, 450 mg/ 45 mL, 10 mg/mL, Cytotoxic Agent, 45 mL Multi Dose Vial	003390450	Y061711AA	February 2013
Carboplatin Injection, 450 mg/ 45 mL, 10 mg/mL, Cytotoxic Agent, 45 mL Multi Dose Vial	003390450	Y061711AB	February 2013
Cytarabine Injection, 1000 mg/ 50 mL, 20 mg/mL, Cytotoxic Agent, 50 mL Vial	003030446	Y131994AA	August 2013
Cytarabine Injection, 1000 mg/ 50 mL, 20 mg/mL, Cytotoxic Agent, 50 mL Vial	003030446	Y141994AA	September 2013
Cytarabine Injection, 1000 mg/ 50 mL, 20 mg/mL, Cytotoxic Agent, 50 mL Vial	003030446	Y151994AA	September 2013
Cytarabine Injection, 1000 mg/ 50 mL, 20 mg/mL, Cytotoxic Agent, 50 mL Vial	003030446	Y161994AA	November 2013
Cytarabine Injection, 1000 mg/ 50 mL, 20 mg/mL, Cytotoxic Agent, 50 mL Vial	003030446	Y171994AA	November 2013
Cytarabine Injection, 1000 mg/ 50 mL, 20 mg/mL, Cytotoxic Agent, 50 mL Vial	003030446	Y181994AA	November 2013
Paclitaxel Injection, 300 mg/ 50 mL, 6 mg/mL, Cytotoxic Agent, 50 mL Multiple Dose Vial	003420450	Y096865AA	August 2013
Paclitaxel Injection, 300 mg/ 50 mL, 6 mg/mL, Cytotoxic Agent, 50 mL Multiple Dose Vial	003420450	Y106865AA	August 2013
Paclitaxel Injection, 300 mg/ 50 mL, 6 mg/mL, Cytotoxic Agent, 50 mL Multiple Dose Vial	003420450	Y116865AA	August 2013
Paclitaxel Injection, 300 mg/ 50 mL, 6 mg/mL, Cytotoxic Agent, 50 mL Multiple Dose Vial	003420450	Y126865AA	September 2013
Paclitaxel Injection, 300 mg/ 50 mL, 6 mg/mL, Cytotoxic Agent, 50 mL Multiple Dose Vial	003420450	Y136865AA	September 2013

Product	List Number	Batch Number	Expiration Date
Paclitaxel Injection, 300 mg/ 50 mL, 6 mg/mL, Cytotoxic Agent, 50 mL Multiple Dose Vial	003420450	Y146865AA	September 2013
Paclitaxel Injection, 300 mg/ 50 mL, 6 mg/mL, Cytotoxic Agent, 50 mL Multiple Dose Vial	003420450	Y156865AA	October 2013
Paclitaxel Injection, 300 mg/ 50 mL, 6 mg/mL, Cytotoxic Agent, 50 mL Multiple Dose Vial	003420450	Y166865AA	November 2013
Paclitaxel Injection, 300 mg/ 50 mL, 6 mg/mL, Cytotoxic Agent, 50 mL Multiple Dose Vial	003420450	Y176865AA	November 2013
Paclitaxel Injection, 300 mg/ 50 mL, 6 mg/mL, Cytotoxic Agent, 50 mL Multiple Dose Vial	003420450	Y186865AA	December 2013
Methotrexate Injection, USP, 1 g/ 40 mL, 25 mg/mL, Cytotoxic Agent, 40 mL Vial	004080441	Y064457AA	October 2013

These lots were distributed in the United States from September 2011 through April 2012. This recall is being conducted as a precautionary measure.